

Notice of Allowability	Application No.	Applicant(s)	
	09/669,051	FRANANO, F. NICHOLAS	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 19 January 2006.
2. ☒ The allowed claim(s) is/are 56,57,60-63,65,66,68 and 70-78.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>12.29.05&1.19.06</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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Examiner's Comments

1. Applicant's Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), filed in this application on 19 January 2006 after the Office action mailed 29 November 2005 is acknowledged and entered. Accordingly an RCE has been established and the action on RCE follows.

CLAIMS STATUS

2. Claims 56-57, 60-63, 65-66, 68 and 70-78 are pending and examined on merits.

Information Disclosure Statement

3. Applicant's Information Disclosures filed on 29 December 2005 under 37 C.F.R. §1.97(d) along with the fee set forth in 37 CFR §1.17(p) and required certification, and on 19 January 2006 under 37 C.F.R. §1.97(a) (4) respectively are entered and considered.

EXAMINER'S REASONS FOR ALLOWANCE

4. The following is Examiner's statement of reasons for allowance:

The prior art considered are:

- i. Thompson et al. (U.S. Patent 5,834,449)
- ii. Trubel et al., European Journal of Vasc. Endovasc. Surg., Volume 10, 1995. Pages 415-423; and
- iii. Dobrin et al., 1994. Cardiovascular Surgery, Volume 2, Number 4, August 1994, Pages 484-488.

Reference (i) is distinguished from the instantly claimed invention because reference (i) teaches a method to treat abnormal abdominal aortic aneurism, a method to inhibit elastolytic activity in vascular tissue to diminish proteolytic activity and inhibit

progression of abnormal vascular dilatation and or aneurysms in an experimental mammal (i.e., rats) via administering tetracycline compounds to said experimental mammal (Abstract, Lines 1-13; Column 8, Lines 50-65). In this reference elastase was administered to induce aneurism. Thus, reference (i) teaches a method that teaches an exactly converse method to that taught in presently claimed invention.

Reference (ii) is distinguished from the instantly claimed invention because reference (ii) teaches a surgical method and does not teach administering a composition comprising elastase in to the sheep subject to treat an obstructed artery or vein via enlarging the entire diameter of the artery or vein rather than only enlarging the lumen of said artery.

Reference (iii) cited *supra* is distinguished from the presently claimed invention of treating an obstructed artery or vein by administering elastase because said reference teaches a method to dilate arteries "excised from cadavers" by administering elastase, wherein said artery (ies) progressively dilate upon treating with elastase but become less distensible, i.e., only the lumen of the artery was dilated not the diameter of entire artery or blood vessel.

5. Thus, the distinguishing feature in instantly claimed invention of "treating an obstructed artery or vein by administering elastase to enlarge the diameter of the artery or vein claimed in independent claim rather than only enlarging the lumen is not taught or fairly suggested by the references of record or those cited *supra*. Therefore, the allowability of previously allowed Claims 56-57, 60-63, 65-66, 68 and 70-78 is maintained

6. Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".


CONCLUSION

7. Claims 56-57, 60-63, 65-66, 68 and 70-78 are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.


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PRIMARY EXAMINER
GROUP 1200

February 2, 2006